Title: Pressure Equipment (Amendment) Regulations 2015 **IA No:** **Lead department or agency:** BIS **Other departments or agencies:**	**Impact Assessment (IA)** **Date:** 10/02/2015 **Stage:** Development/Options **Source of intervention:** EU **Type of measure:** Secondary Legislation **Contact for enquiries:** Andrew Lunnon, Product Regulations, BIS. 020 7215 0158, andrew.lunnon@bis.gsi.gov.uk

Summary: Intervention and Options

RPC Opinion: Awaiting Scrutiny

Cost of Preferred (or more likely) Option				
Total Net Present Value	**Business Net Present Value**	**Net cost to business per year** (EANCB on 2009 prices)	**In scope of One-In, Two-Out?**	**Measure qualifies as**
£-2.84m	£-2.84m	£0.24m	No	NA

What is the problem under consideration? Why is government intervention necessary?

The proposed legislation will implement part of a new Pressure Equipment Directive (new PED – 2014/68/EU) which aligns the classification of equipment provisions to the introduction of Regulation 1272/2008/EC on Classification, Labelling and Packaging of Substances and Mixtures (CLP). The new PED will revoke the current basis for product classification in the old PED on 1 June 2015 and the UK implementing Regulations need to be updated to reflect this by 28 February 2015. The CLP implements new UN obligations and its timing is driven by the UN dates.

What are the policy objectives and the intended effects?

The proposed amending Regulations will implement the updated references to the CLP Regulation in UK law. This will involve a revision to two of the definitions in the existing Regulations.

The new Directive sets out the essential health and safety requirements for pressure equipment and provides for conformity assessments of equipment according to the volume and pressure of the equipment, plus the contents.

What policy options have been considered, including any alternatives to regulation? Please justify preferred option (further details in Evidence Base)

The UK is required to implement the revised Directive, which does not give the option of using alternatives to regulation.

Will the policy be reviewed? It will not be reviewed. **If applicable, set review date:** n/a

Does implementation go beyond minimum EU requirements?			No			
Are any of these organisations in scope? If Micros not exempted set out reason in Evidence Base.	**Micro** Yes	**< 20** Yes	**Small** Yes	**Medium** Yes	**Large** Yes	
What is the CO_2 equivalent change in greenhouse gas emissions? (Million tonnes CO_2 equivalent) N/A			**Traded:** n/a		**Non-traded:** n/a	

I have read the Impact Assessment and I am satisfied that, given the available evidence, it represents a reasonable view of the likely costs, benefits and impact of the leading options.

Signed by the responsible MINISTER Matthew Hancock Date: 25 February 2015

Summary: Analysis & Evidence

Policy Option 1

Description:

FULL ECONOMIC ASSESSMENT

Price Base Year 2014	PV Base Year 2014	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low: -0.95	**High:** -4.48	**Best Estimate:** -2.84

COSTS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	Optional		0.1	**0.9**
High	Optional		0.5	**4.5**
Best Estimate			0.3	**2.8**

Description and scale of key monetised costs by 'main affected groups'

There are on-going costs in terms of some equipment manufacturers having to meet higher levels of conformity assessment requiring greater involvement of Notified Bodies but discussions with stakeholders and evidence from the EU IA suggest that such costs will be limited with no such costs for the majority of manufacturers. A range of possible estimates have been provided based on EU IA estimates amended to reflect the size of the UK market for pressure equipment.

Other key non-monetised costs by 'main affected groups'

There are likely to be one off costs in terms of familiarisation, training and changes to equipment literature but it has not been possible to monetise these even after contacting stakeholders. Discussions with stakeholders have suggested that in many cases these will be absorbed as part of business as usual training and updates.

BENEFITS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	Optional		Optional	**Optional**
High	Optional		Optional	**Optional**
Best Estimate	0		0	**0**

Description and scale of key monetised benefits by 'main affected groups'

Maximum of 5 lines

Other key non-monetised benefits by 'main affected groups'

Benefits relate largely to the greater international conformity for all EU pressure equipment manufacturers that will result as the CLP will bring them in line with the UN Globally Harmonised System of Classification and Labelling of Chemicals. This in turn should ensure greater levels of market competition and opportunities for EU manufacturers to compete

Key assumptions/sensitivities/risks **Discount rate (%)** 3.5

The key assumptions made relate to the number of manufacturers affected by the change in substance classification and the additional costs associated with any further assessment that might be required. The IA relies on EU IA assumptions and assumes that costs of compliance are equally distributed across the EU so that the UK's share is equal to its share of sales of pressure equipment.

BUSINESS ASSESSMENT (Option 1)

Direct impact on business (Equivalent Annual) £m:			In scope of OITO?	Measure qualifies as
Costs: 0.2	**Benefits:** 0	**Net:** -0.2	No	N/A

Evidence Base (for summary sheets)

Problem under consideration;

The Pressure Equipment Directive is regarded as a successful Single Market Directive as it harmonises across the EU safety requirements in an area that was covered previously by disparate and conflicting national regulations. This has brought benefits to manufacturers by simplifying a complex area and creating a level playing field.

The pressure equipment sector in the UK is relatively small and has declined in recent years from 843 to 653 manufacturers, although with a growing turnover (£4.5bn to £5bn) and employment (28k to 31k). As with most sectors the majority of these are SMEs (575).

The proposal will implement part of the new Pressure Equipment Directive (PED - 2014/68/EU) through an amendment to the UK Pressure Equipment Regulations 1999. The Pressure Equipment Directives (old and new) are Single Market legislation regulating the safety of pressure equipment (pressure vessels, boilers, piping and associated valves and safety accessories) across the EU, replacing disparate national safety requirements. The Directive sets out the essential health and safety requirements for pressure equipment and provides for conformity assessments of equipment according to the volume and pressure of the equipment, plus the contents. In the old Directive pressure equipment containing certain classifications of hazardous substances taken from the Dangerous Substances Directive (67/548/EEC) – for example, flammable, corrosive – are subject to a more rigorous conformity assessment.

The Dangerous Substances Directive (DSD) is to be revoked by Regulation 1272/2008/EC on the Classification, Labelling and Packaging of Substances and Mixtures (CLP) on 1 June 2015 and so the references to the DSD in the new PED have been updated to reflect this.

The PED places equipment in two groups – Group 1 and Group 2. Group 1 covers equipment that contains substances that fall within specific hazard classifications as identified under the DSD (e.g. flammable, explosive, toxic), shortly to be replaced by updated, but similar classifications under the CLP. Group 2 covers equipment containing all substances not in Group 1.

Rationale for intervention;

The proposed legislation will implement part of a new Pressure Equipment Directive (new PED – 2014/68/EU) which aligns the classification of equipment provisions to the introduction of Regulation 1272/2008/EC on Classification, Labelling and Packaging of Substances and Mixtures (CLP). The new PED will revoke the current basis for product classification in the old PED on 1 June 2015 and the UK implementing Regulations need to be updated to reflect this by 28 February 2015. The CLP implements new UN obligations and its timing is driven by the UN dates. It would be confusing to business and legally unsound if the UK implementing Regulations did not mirror this change. Business could not export its products freely within the EU. The Commission could infract the UK if we did not implement the changes to the Directive.

Policy objective;

The proposed amending Regulations will implement the updated references to the CLP Regulation in UK law. This will involve a revision to two of the definitions in the existing Regulations. The CLP is the EU implementation of the updated UN Globally Harmonised System of Classification and Labelling of Chemicals. The previous version was implemented under the DSD. The PED is being amended to ensure that the correct references can be used for classifying pressure equipment.

Description of options considered (including do nothing);

The UK is required to implement the revised Directive, which does not give the option of using alternatives to regulation.

Monetised and non-monetised costs and benefits of each option (including administrative burden);

The administrative impacts are largely expected to be one-off in nature (in terms of updating guidance, additional training and familiarisation with the new directive) and will fall mainly on manufacturers of pressure equipment. Such costs are likely to affect all 650 businesses in the sector. These one off costs are considered to be small given that changes to guidance and additional training will take place anyway as part of routine updating within the industry. Discussions with stakeholders through the informal consultation process have not provided any evidence on which to try to quantify such impacts but have confirmed the view that they are likely to be relatively small and easily absorbed by businesses which are used to operating in a regulated environment.

The EU undertook a significant consultation exercise with the industry as part of the negotiation of the new directive and found that compliance costs (ongoing) were expected to be more significant for those affected. These increased compliance costs are expected to occur in terms of equipment manufacturers having to meet higher levels of conformity assessment when placing new equipment onto the EU market. For those manufacturers affected (whose equipment will now be used with Group 1 substances) this is likely to require greater involvement of Notified Bodies (who test equipment before it can be placed on the market) and changes to equipment marking. However, discussions with UK stakeholders and evidence from the EU IA suggest that such costs will be limited in practice with no such costs for the majority of manufacturers.

Quantifying the size of such costs is difficult as it requires an estimate of the number of manufacturers likely to be affected and an estimate of the likely increase in compliance costs. Discussions with stakeholders suggest that many manufacturers are likely to be already producing equipment that needs to meet the higher conformity requirements for Group 1 substances either to appeal to the widest possible group of customers or to meet customer demands for the higher safety specification. In these cases such manufacturers won't therefore be significantly affected by the change in substance categorisation (see EU IA http://ec.europa.eu/enterprise/sectors/pressure-and-gas/files/ped/ia-study-alignment-clp_en.pdf for further information).

Consultation responses and more detailed discussions with stakeholders have also suggested that some equipment manufacturers may also be able to amend the design and operation of their equipment by adjusting operational volumes and pressures to remain in the original classification and thereby avoiding the need for additional assessment costs. Furthermore most Group 1 fluids, as currently categorised according to the DSD classification, will remain Group 1 fluids when the PED is aligned to the CLP Regulation. There are, however, a number of substances in 'boundary areas' where changes in the group classification may occur. Following analysis by the Commission, the number of such substances is estimated to be less than 10% of the total and even this is thought to be a very conservative estimate.

In addition, not all of these substances will be used in pressure equipment, so the number will be even lower. Any such costs will also be offset to a limited extent by the re-classification of certain substances from category 1 to category 2 which would imply a lower level of assessment and associated costs for some manufacturers, although as set out above consumer preferences might mean that manufacturers continue with the higher level of safety assessment and forgo any cost savings.

As part of the development of the revised regulations the EU undertook a significant amount of consultation with industry bodies (including those in the UK) and had only limited evidence presented of likely negative impacts (the biggest reported concern was increased compliance costs as explained above). Further research by the EU suggested that around 75% of manufacturers were unlikely to be affected directly by the change in substance classifications as they would be manufacturing equipment suitable for the Group 1 higher risk substances by default or at the request of customers anyway. Of the remaining 25% it was thought that only a fifth would be manufacturing equipment for use with substances which are likely to be reclassified to Group 1 implying greater compliance costs. This implies that only 5% (20% of 25%) of all manufacturers of pressure equipment are likely to face increased compliance costs. This is likely to represent the upper end of a range of estimates for the reasons set out above.

Further analysis as part of the EU IA suggests that the increase in compliance costs is likely to be of the order of 5%. The EU impact assessment calculates a baseline cost of compliance with the current directive and then uses the assumptions set out above to calculate a potential increase in compliance costs of Euro 8.5m per annum for European equipment manufacturers as a whole.

By assuming that costs are equally distributed across all EU manufacturers it is possible to use the EU wide figures to produce a possible compliance cost for the UK of €0.4m (or £0.31m) per annum (the UK represents 5% of EU manufacturers of pressure equipment so the cost attributed to these manufacturers on a pro rata basis is 5% of €8.5m). The EU IA however accepts that this may overestimate the likely costs – it provides a possible range of increased compliance costs of €2.7 to €13.3m suggesting a UK range of €0.14 to €0.67m (or £0.1m to £0.5m assuming an exchange rate of £1 to €1.27) per annum. Discussions with UK stakeholders however would suggest that compliance costs are likely to be the lower end of this range of possible costs.

Benefits

Benefits relate largely to the greater international conformity for all EU pressure equipment manufacturers that will result as the CLP will bring them in line with the UN Globally Harmonised System of Classification and Labelling of Chemicals. The recategorisation of substances between group 1 and group 2 and a more detailed classification of substances within Group 1 might also be expected to bring benefits to users of the equipment by reducing the risk of exposure to toxic substances through improved levels of information.

An industry stakeholder has also suggested that for those parts of the pressure equipment industry dealing with new chemicals the aligned classification system will mean that they can more easily categorise them, ensuring compliance with the regulatory regime and reducing any regulatory uncertainty. Thus a key benefit of these changes is that there is one classification system for European manufacturers regardless of which market is supplied.

This in turn should mean more effective levels of competition between manufacturers competing on a level playing field and greater opportunities for European manufacturers to supply international markets with which the EU classification system will be compliant.

Given the rather intangible nature of these benefits it has not been possible to quantify them and neither has the EU IA attempted to do so.

Risks and assumptions;

The key assumptions made relate to the number of manufacturers affected by the change in substance classification and the additional costs associated with any further assessment that might be required. The EU IA assumes that 5% of manufacturers will be affected by the change in substance classifications and that those affected will incur additional compliance costs of 5%.

The EU impact assessment makes clear that there are few reliable data on the pressure equipment industry and market data on these sectors is almost impossible to obtain. Information sources are restricted as there is no single EU professional association. In addition, attempts undertaken in the past to quantify the market for pressure equipment in Europe have failed. Because of this some estimates have been made on the basis of Eurostat data but are considered indicative of the scale of the sector.

The other key assumption is that the UK's share of compliance costs is proportional to its share of the pressure equipment manufacturers. Given the limited data on this sector there is no reason to believe that the structure of the UK pressure equipment sector differs significantly from that in wider Europe in a way that would affect this assumption.

Rationale and evidence that justify the level of analysis used in the IA (proportionality approach);

This is a relatively small market for which there is limited market information. Significant stakeholder engagement has been undertaken as part of the development of the revised directive at both the UK and EU level but only limited evidence on likely costs and benefits has been identified. This IA therefore relies largely on the analysis undertaken by the EU which has been quite significant in terms of attempts to identify likely increased compliance costs. Further analysis would have been resource intensive and disproportionate given the size of the sector and the relatively limited changes being brought in by the new directive.

Direct costs and benefits to business calculations (following OITO methodology);

We have been unable to quantify the benefits of these changes but the direct costs to business range from £0.1m to £0.5 m per annum with a best estimate of £0.3m. This gives a net present value cost of £2.84m per annum and an EANCB of £0.2m.

Wider impacts

The proposed Regulations will ensure continuity in the legislation by updating the UK legislation in line with EU and UN references, thus minimising disruption and confusion for manufacturers.

Summary and preferred option with description of implementation plan.

Given that this is an EU regulation that the UK is required to implement or face infraction by the EU and there is no flexibility around implementation the preferred option remains Option 1.

The Pressure Equipment (Amendment) Regulations 2015 are the first part of the implementation of the revised PED. There will be further regulations to implement the rest of the Directive in time to meet an implementation deadline of July 2016. These will harmonise the PED with other Single Market Directives under the New Legislative Framework which seeks to introduce common definitions between Directives (e.g. of manufacturer, importer etc), as well as introducing a common set of measures to strengthen enforcement and appointment of Conformity Assessment Bodies. The 2016 Regulations will revoke and replace these Regulations, so there is no plan to review them. The 2016 Regulations will be subject to review in due course.